Complete Summary

GUIDELINE TITLE

Type 2 diabetes practice guidelines.

BIBLIOGRAPHIC SOURCE(S)

International Diabetes Center. Type 2 diabetes practice guidelines. Minneapolis (MN): International Diabetes Center; 2003. 1 p.

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Staged diabetes management: a systematic approach. Minneapolis (MN): Matrex, International Diabetes Center; 2000. Type 2 diabetes practice guidelines. p. 63-131.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- February 26, 2008, Avandia (rosiglitazone): A new Medication Guide for Avandia must be provided with each prescription that is dispensed due to the U.S. Food and Drug Administration's (FDA's) determination that this medication could pose a serious and significant public health concern.
- November 14, 2007, Avandia (rosiglitazone): New information has been added to the existing boxed warning in Avandia's prescribing information about potential increased risk for heart attacks.
- August 14, 2007, Thiazolidinedione class of antidiabetic drugs: Addition of a boxed warning to the updated label of the entire thiazolidinedione class of antidiabetic drugs to warn of the risks of heart failure.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Type 2 diabetes mellitus

GUIDELINE CATEGORY

Diagnosis
Evaluation
Management
Screening
Treatment

CLINICAL SPECIALTY

Endocrinology
Family Practice
Internal Medicine
Pediatrics

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Dietitians
Managed Care Organizations
Nurses
Pharmacists
Physician Assistants
Physicians
Psychologists/Non-physician Behavioral Health Clinicians
Social Workers

GUIDELINE OBJECTIVE(S)

Staged Diabetes Management is a systematic approach to detecting and treating diabetes using practice guidelines and clinical pathways that reflects the changing responsibilities of the primary care provider and the primary care team. The purpose of Staged Diabetes Management is to:

- Provide a systematic, data-based approach for clinical decision making in the treatment of diabetes and its complications

- Provide a consistent set of scientifically based practice guidelines that can be adapted by a community according to its resources
- Identify appropriate criteria for altering therapies during three treatment phases: Start, Adjust, and Maintain
- Provide a common Master DecisionPath for the type of diabetes that both patients and providers can use to understand treatment options, to enhance communication, and to optimize therapies
- Facilitate the detection and treatment of diabetes and its complications by primary care providers, in consultation with specialists (comanagement)

TARGET POPULATION

Children, adolescents, and adults with suspected or documented type 2 diabetes mellitus

INTERVENTIONS AND PRACTICES CONSIDERED

1. Screening and diagnosis
    - Screening for risk factors (familial and personal)
    - Fasting plasma glucose; casual plasma glucose, oral glucose tolerance test
    - Urinary ketones
    - Assessment of signs and symptoms
2. Staged treatment
    - Medical nutrition and activity therapy
    - Oral agent monotherapy
        - Biguanide or thiazolidinedione
        - Sulfonylurea, nateglinide, repaglinide or –glucosidase inhibitor
    - Combination therapy
        - Combination oral agents
        - Sulfonylurea plus (+) biguanide, thiazolidinedione or -glucosidase inhibitor
        - Metformin + sulfonylurea, nateglinide, repaglinide, thiazolidinedione or –glucosidase inhibitor
        - Thiazolidinedione + sulfonylurea or biguanide
        - Repaglinide or nateglinide + biguanide
        - –Glucosidase inhibitor + sulfonylurea or biguanide
    - Staged insulin therapy (monotherapy or combined with oral agents)
        - Lispro or Aspart
        - Regular human insulin
        - Neutral protamine Hagedorn (NPH) insulin
        - Glargine
        - Lente insulin
3. Targeting and monitoring blood glucose control
    - Self-monitored blood glucose (metered with memory and log book)
    - Hemoglobin A_{1c} or total glycosylated hemoglobin
    - Blood pressure
    - Lipids
    - Urinary ketones
4. Follow-up
    - Blood glucose
    - Weight or body mass index

- History and physical examination
- Fasting lipid profile
- Albuminuria
- Eye, dental, neurological, foot examination
- Adult immunization
- Referral for diabetes and nutrition education

5. Complications surveillance
6. Patient education (diabetes, exercise, nutrition)
7. Psychological and social assessment

MAJOR OUTCOMES CONSIDERED

Intermediate Outcome Measures of Blood Glucose Control

- Hemoglobin A_{1c}
- Blood glucose, by self-monitored blood glucose and casual (random) and fasting plasma glucose
- Urinary ketones

Long-term Outcome Measures

- Retinal changes
- Renal changes
- Neurological changes
- Cardiovascular disease
- Peripheral vascular disease
- Foot problems (ulcers, deformities, infections)

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus
Subjective Review

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not applicable

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

A team of endocrinologists, family physicians, clinical nurse specialists, and dieticians joined together in 1988 to identify the therapeutic principles that lie at the core of diabetes management. Specialists joined the team as needed, including a perinatologist, an epidemiologist, and a psychologist, among others. The team investigated current approaches to the treatment of type 1 diabetes, type 2 diabetes, and diabetes in pregnancy. At biweekly conferences over a period of 5 months, each step in diagnosing and treating each type of diabetes was carefully delineated.

Key decisions points were placed on flow charts termed "DecisionPaths." These DecisionPaths contained the following:

- Treatment modalities
- Criteria for initiating treatment
- Criteria for changing treatment
- Key clinical decision points
- Information about establishing, monitoring, and evaluating therapeutic goals
- Recommended follow-up

Changes in the original design of Staged Diabetes Management since its initiation in 1988 have been made to reflect additional patient data collected during clinical trials and implementation studies.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Clinical Validation-Trial Implementation Period

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Since its initiation in 1988, Staged Diabetes Management has undergone clinical trials and implementation studies in more than 200 sites worldwide. The results have led to changes in the original design of Staged Diabetes Management and are reflected in the guideline text. Nevertheless, the basic principles upon which Staged Diabetes Management is founded remain intact.

To continue to refine this systematic approach to clinical decision-making, the records of randomly selected patients seen in a diabetes specialty center are periodically evaluated. These are supplemented by data on more than five thousand individuals with diabetes treated in primary care centers in accordance with Staged Diabetes Management protocols.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The following is an outline of practice guidelines for management of type 2 diabetes mellitus. A detailed management plan and accompanying DecisionPaths can be found in the original guidelines:

Screening

Screen all patients every 3 years starting at age 45; if risk factors present, start earlier and screen annually.

Risk Factors

- Family history of type 2 diabetes (especially first-degree relatives)
- Body mass index >25 kg/m^2 (especially waist-to-hip ratio >1)
- Age (risk increases with age)
- Hypertension ($\geq$140/90 mm Hg)
- Dyslipidemia (high-density lipoprotein $\leq$35 mg/dL and/or triglyceride $\geq$250 mg/dL)
- Previous impaired fasting glucose with fasting plasma glucose 110 to 125 mg/dL
- Previous impaired glucose tolerance with oral glucose tolerance test 2 hour glucose value 140 to 199 mg/dL
- Previous gestational diabetes: macrosomic or large-for-gestational age infant (>9lbs.)
- Acanthosis nigricans/polycystic ovary syndrome (PCOS)
- History of vascular disease
- American Indian or Alaska Native, African American, Hispanic, Asian, Pacific Islander

Diagnosis

Plasma Glucose

Casual ≥200 mg/dL plus symptoms, fasting ≥126 mg/dL, or 75 g Oral Glucose Tolerance Test 2 hour glucose value ≥200 mg/dL; if positive, confirm diagnosis with casual or fasting plasma glucose on subsequent day within one week.

Symptoms

Often none

Common: Blurred vision, urinary tract infection, yeast infection, dry/itchy skin, numbness or tingling in extremities, fatigue

Occasional: Increased urination, thirst, and appetite; nocturia; weight loss

Urine Ketones

Usually negative

Treatment Options

Medical nutrition therapy and activity, oral agent monotherapy, combination therapy (oral agents or oral agent-insulin), insulin stages 2, 3, 4 (see Type 2 Master DecisionPath in the original guideline document)

Targets

Self-Monitored Blood Glucose

- More than 50% of self-monitored blood glucose values within target range
- Pre-meal: 70 to140 mg/dL
- Post-meal (2 hr after start of meal): <160 mg/dL
- Bedtime: 100 to 160 mg/dL
- No severe (assisted) or nocturnal hypoglycemia

Adjust pre-meal target upwards (e.g. 100 to 160 mg/dL) if frail elderly, cognitive disorders, or other medical concerns (cardiac disease, stroke, hypoglycemia unawareness, end-stage renal disease)

Hemoglobin A_{1c}

- Within 1.0% point of upper limit of normal (e.g. normal 6.0%; target <7.0%)
- Frequency: every 3 to 4 months
- Use hemoglobin A_{1c} to verify self-monitored blood glucose data

Blood Pressure

<130/80 mm Hg

Lipids

Low-density lipoprotein <100 mg/dL; high-density lipoprotein >40 mg/dL; triglyceride <150 mg/dL

Monitoring

Self-Monitored Blood Glucose

2 to 4 times/day (e.g., before breakfast, before main meal, 2 hrs after main meal); if on insulin, check 3 a.m. self-monitored blood glucose as needed; self-monitored blood glucose may be modified due to cost, technical ability, or availability of meters.

Method

Meter with memory that is downloadable and log book

Follow Up

Monthly

Office visit during Adjust Phase (weekly phone contact may be necessary)

Every 3 Months

Hypoglycemia, medications, weight or body mass index, blood pressure, self-monitored blood glucose data (download and check meter), hemoglobin A_{1c}, eye and foot screen, medical nutrition therapy, preconception planning for women of childbearing age, smoking cessation counseling, aspirin therapy

Yearly

In addition to the 3 month follow-up, complete the following: history and physical, fasting lipid profile, albuminuria screen, dilated eye examination, dental examination, neurologic assessment, complete foot examination (pulses, sensation, and inspection), referral for diabetes and nutrition education, adult immunizations

Complications Surveillance

Cardiovascular, renal, retinal, neurological, foot, oral, and dermatological

CLINICAL ALGORITHM(S)

Algorithms are provided for management of type 2 diabetes mellitus in the form of a Master DecisionPath and separate, detailed DecisionPaths for:

- Screening and Diagnosis
- Master DecisionPath for Individuals Under Age 18
- Screening and Diagnosis for Individuals Under Age 18
- Impaired Glucose Homeostasis/Start

- Medical Nutrition Therapy (Start)
- Medical Nutrition Therapy (Adjust)
- Exercise Assessment
- Oral Agent Selection for Individuals 18 Years and Older
- Insulin Stage 2/Start
- Insulin Stage 2/ Adjust
- Insulin Stage 3A/Start
- Treating Hypoglycemia
- Medical Nutrition Adherence Assessment
- Psychological and Social Assessment
- Pregestational and Gestational Diabetes

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated for each recommendation. However, throughout the guideline document, the evidence used as the basis for the recommendations is discussed.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Improved detection and control of type 2 diabetes
- Reduction in diabetic complications: epidemiological data show that for each 1 percentage point decrease in hemoglobin A_{1c}, there is a 23% reduction in retinopathy and a marginal reduction in myocardial infarction risk. Other major studies have shown dramatic complications risk reductions with improved glycemic control. Reductions in hemoglobin A_{1c} may also reduce the progression of microvascular disease.

Subgroups Most Likely to Benefit

Individuals at high risk for developing type 2 diabetes, including those with a family history of type 2 diabetes and those whose race or ethnic background might predispose them to developing type 2 diabetes (American Indians, Hispanics, African Americans, Asians, Pacific Islanders, Native Hawaiians)

POTENTIAL HARMS

The following adverse effects are identified for the various drug classes used to treat type 2 diabetes:

- *Sulfonylureas*: All sulfonylureas can cause hypoglycemia, although second- and third-generation agents may result in less hypoglycemia than first-generation agents.
- *Biguanides (metformin)*: Metformin can lead to hypoglycemia when used in combination with a sulfonylurea or insulin. It has been associated with lactic acidosis in only a small number of cases.

- *Meglitinides (repaglinide)*: The incidence of hypoglycemia with repaglinide is comparable to that of second-generation sulfonylureas.
- *Alpha-glucosidase inhibitors (acarbose, miglitol)*: The predominant side effects include abdominal pain, diarrhea, and flatulence.
- Insulin can cause mild, moderate, or severe hypoglycemia. Symptoms of mild hypoglycemia include shaking, sweating, blurred vision, and irritability. Symptoms of moderate hypoglycemia are confusion, tiredness, yawning, poor coordination, headache, double vision, and combativeness. Severe hypoglycemia can lead to unconsciousness or seizures.

Subgroups Most Likely to be Harmed

- Sulfonylureas should be used with caution in patients with allergies to sulfa drugs.
- Patients with heart, liver (including alcoholism or alcohol abuse), kidney (serum creatinine >1.4 mg/dL [120 micromole/L]), or pulmonary disease may be at increased risk of lactic acidosis with metformin. Patients over 80 years of age should not take metformin unless creatinine clearance demonstrates that renal function is not impaired.
- Thiazolidinediones (pioglitazone, rosiglitazone): Because of the potential for hepatotoxicity, caution should be used when starting thiazolidinedione therapy if alanine transaminase levels are mildly elevated (1 to 2.5 times the upper limit of normal) and therapy should not be initiated if alanine transaminase levels are >2.5 times the upper limit of normal. For rosiglitazone and pioglitazone therapy, alanine transaminase levels should be determined every other month for the first year of therapy and periodically thereafter. Increased alanine transaminase monitoring may be required if alanine transaminase levels increase during treatment with thiazolidinedione. Discontinue thiazolidinedione therapy if alanine transaminase levels exceed three times the upper limit of normal.

CONTRAINDICATIONS

CONTRAINDICATIONS

- All oral hypoglycemic agents are contraindicated during pregnancy.
- Sulfonylureas are contraindicated in the presence of severe renal disease or hepatic dysfunction.
- Metformin is contraindicated in patients with congestive heart failure who require pharmacologic treatment. Additionally, metformin is not approved for use in pregnancy and during lactation.
- Contraindications to acarbose include pregnancy and lactation, severe renal disease, chronic intestinal disease, and liver disease.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

These Guidelines should not be interpreted as including all available and proper methods of diabetes care. The decision regarding any specific treatment modality should be made by the health care professional with consideration of the

particular circumstances presented by the patient and the needs and resources particular to the community or institution.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

To fully implement Staged Diabetes Management requires participation in the Staged Diabetes Management process. This entails orientation to Staged Diabetes Management principles as well as assessing current practices, customizing elements of Staged Diabetes Management for the community and identifying possible obstacles to implementation and follow-up.

Commitment to improving diabetes care is crucial to the success of Staged Diabetes Management in any community, and the key is building consensus. The goal of Staged Diabetes Management is to ensure consistent, high-quality diabetes care. To do this, all providers in the community need to become acquainted with and follow the same guidelines. A process based on consensus building is recommended in order to optimize the adoption of Staged Diabetes Management.

Starting and staying with successful Staged Diabetes Management requires six steps:

- Community diabetes care needs assessment
- Group formation
- Orientation to Staged Diabetes Management
- Customization of Staged Diabetes Management
- Implementation of Staged Diabetes Management
- Evaluation of Staged Diabetes Management

Note: A detailed implementation plan can be found in the original guidelines.

IMPLEMENTATION TOOLS

Clinical Algorithm

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

International Diabetes Center. Type 2 diabetes practice guidelines. Minneapolis (MN): International Diabetes Center; 2003. 1 p.

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2000 (revised 2003)

GUIDELINE DEVELOPER(S)

International Diabetes Center - Private Nonprofit Organization

GUIDELINE DEVELOPER COMMENT

The International Diabetes Center is part of the Institute for Research and Education HealthSystem Minnesota. HealthSystem Minnesota, an integrated care system, also includes Methodist Hospital, Park Nicollet Clinic, and The Foundation.

The International Diabetes Center is a World Health Organization (WHO) Collaborating Center for Diabetes Education, Translation and Computer Technology.

SOURCE(S) OF FUNDING

This publication is supported by an unrestricted educational grant from Becton Dickinson and Company.

GUIDELINE COMMITTEE

Not stated

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Authors: Roger S. Mazze, PhD, Ellie S. Strock, RN, ANP, CDE; Gregg D. Simonson, PhD, Richard M. Bergenstal, MD, Donnell D. Etzwiler, MD

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Staged diabetes management: a systematic approach. Minneapolis (MN): Matrex, International Diabetes Center; 2000. Type 2 diabetes practice guidelines. p. 63-131.

GUIDELINE AVAILABILITY

Print copies: Available for purchase from the International Diabetes Center, 3800 Park Nicollet Boulevard, Minneapolis, MN 55416-2699; (888) 825-6315 (U.S. only); Web site: www.idcdiabetes.org.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on May 21, 2001. This summary was updated by ECRI on February 18, 2004. The information was verified by the guideline developer on March 11, 2004. This summary was updated by ECRI on January 11, 2006 following the U.S. Food and Drug Administration advisory on rosiglitazone. This summary was updated by ECRI Institute on September 5, 2007 following the U.S. Food and Drug Administration advisory on the Thiazolidinedione class of antidiabetic drugs. This summary was updated by ECRI Institute on November 28, 2007 following the U.S. Food and Drug Administration advisory on the Avandia (rosiglitazone maleate) Tablets. This summary was updated by ECRI Institute on March 10, 2008 following the U.S. Food and Drug Administration advisory on Avandia (rosiglitazone maleate).

COPYRIGHT STATEMENT

This NGC summary is based on the original guideline, which is subject to the guideline developer's copyright restrictions.

Copyright 2000. International Diabetes Center, Institute for Research and Education. All rights reserved. No part of these Guidelines may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, photocopying, recording or otherwise, without prior written permissions of the International Diabetes Center. These Guidelines should not be interpreted as including all available and proper methods of diabetes care. The decision regarding any specific treatment modality must be made by the health care professional with consideration of the particular circumstances presented by the patient and the needs and resources particular to the community or institution.

DISCLAIMER

NGC DISCLAIMER

The National Guideline Clearinghouse™ (NGC) does not develop, produce, approve, or endorse the guidelines represented on this site.

All guidelines summarized by NGC and hosted on our site are produced under the auspices of medical specialty societies, relevant professional associations, public or private organizations, other government agencies, health care organizations or plans, and similar entities.

Guidelines represented on the NGC Web site are submitted by guideline developers, and are screened solely to determine that they meet the NGC Inclusion Criteria which may be found at http://www.guideline.gov/about/inclusion.aspx .

NGC, AHRQ, and its contractor ECRI Institute make no warranties concerning the content or clinical efficacy or effectiveness of the clinical practice guidelines and related materials represented on this site. Moreover, the views and opinions of developers or authors of guidelines represented on this site do not necessarily state or reflect those of NGC, AHRQ, or its contractor ECRI Institute, and inclusion or hosting of guidelines in NGC may not be used for advertising or commercial endorsement purposes.

Readers with questions regarding guideline content are directed to contact the guideline developer.

© 1998-2008 National Guideline Clearinghouse

Date Modified: 10/6/2008